

Atty. Dkt. No. EPI30078
(formerly TSRI 184.2C2)

REMARKS

After amending the claims as set forth above, claims 79, 81-85, 87-90 and 93-95 will be pending in this application. Claims 79, 81-84 and 87-89 have been amended to clarify the invention for better understanding by the Examiner. No new matter has been added by these changes. Amendment of the claims to recite a "product comprising a single immunoglobulin polypeptide" finds basis throughout the specification. For example, the specification teaches immunoglobulin multimeric proteins comprising heavy chains, which may associate with other heavy chains and/or with other polypeptides such as a J chain or a secretory component (see e.g., page 32, lines 12-19); These associations are well known in the art. See, e.g., Faguet et al., Blood (1977) Apr;49(4):495-505 (Abstract attached as Exhibit A). Furthermore, Applicants submit that the terms "derived" and "obtained" have similar meaning and scope in the context of the claim.

NON-STATUTORY DOUBLE PATENTING

Claims 79, 81-85, 87-90 and 93-95 remain rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 21-66 of copending U.S. application serial no. 09/512,736 for reasons explained in an Office Action dated July 5, 2001. The Examiner acknowledges Applicants' previous request in a reply of March 4, 2002 (page 9) to enter the terminal disclaimer in the case.

Applicants respectfully submit that the examiner's prior reasoning is no longer applicable and that the terminal disclaimer be removed from the case.

On August 7, 2002, the Examiner issued a restriction requirement dividing the claims into two groups on the basis that claims reciting cells expressing a heavy and light chain are unrelated to claims that recite cells expressing only a heavy chain. In related copending application serial no. 09/512,736, the Examiner, on August 13, 2002 (referring to July 5, 2002), reiterated restriction of the claims into three groups separable as involving immunoglobulin heavy and light chain (group I), heavy chain alone (group II) and light chain alone (group III). Thus, the Patent Office has taken the position that claims involving different immunoglobulin forms such as a heterodimeric heavy and light chain

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immunoglobulin or a single chain light or heavy (but not both) immunoglobulin are patentably distinct inventions.

The instantly pending claims are directed to a plant comprising plant cells containing nucleotide sequence encoding an immunoglobulin heavy chain of an antigen-specific immunoglobulin comprising a heavy and light chain wherein the cells do not contain nucleic acid encoding a light chain. In contrast, claims 21-66 of copending U.S. application serial no. 09/512,736, which have since been replaced with claims 53, 56, 63-65, 67, 68, 76 and 85-92, are directed to a plant comprising plant cells containing nucleotide sequence encoding an immunoglobulin light chain of an antigen-specific immunoglobulin comprising a heavy and light chain wherein the cells do not contain nucleic acid encoding a heavy chain. Thus, the claims of copending U.S. application serial no. 09/512,736 and those currently pending in the instant application are directed to non-overlapping subject matter.

It is further noted that a provisional rejection for obviousness-type double patenting issued in copending U.S. application serial no. 09/512,736 and involving the claims of the instant application has been withdrawn over these same arguments. See "Detailed Action" page 2, Office Action September 2, 2003 in U.S. serial No. 09/512,736.

In view of the above, the Examiner is respectfully requested to withdraw the rejection and remove the terminal disclaimer from the case.

REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The rejection of claim 83 and dependent claims under 35 U.S.C. § 112, second paragraph as being indefinite because of the word "derived" is respectfully traversed. The Examiner alleges that "derived" does not indicate how much of the heavy chain is "derived" from by the antigen specific immunoglobulin. It is respectfully submitted that this constitutes circular reasoning and does not state any basis to support why derived is indefinite. Nevertheless, Applicant has amended the claim to recite that the

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immunoglobulin heavy chain is "obtained" from an antigen specific immunoglobulin. It is Applicant's position that both terms mean the same in this context.

Furthermore, Applicant maintains that "derived" is not indefinite for the reasons discussed in the previous response filed on April 2, 2003. When one skilled in the art would understand all of the language in the claims when read in light of the specification, a claim is not indefinite. *Rosemount Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1547, 221 USPQ 1, 7 (Fed. Cir. 1984), *Caterpillar Tractor Co. v. Berco, S.P.A.*, 714 F.2d 1110, 1116, 219 USPQ 185, 188 (Fed. Cir. 1983). Accordingly, the rejection is without basis and should be withdrawn.

The rejection of claims 84 and 85-87 under 35 U.S.C. § 112, second paragraph as being indefinite in the recitation of "is a multimer" is respectfully traversed. It is the Examiner's position that multimer is inconsistent with single polypeptide product and not with a product comprising a single polypeptide. Although Applicants respectfully disagree, in order to advance prosecution of the case, the claims have been amended to recite a "product comprising a single immunoglobulin polypeptide."

Claim 83 and dependent claims have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite because it is allegedly unclear whether the phrase "wherein said plant cells do not contain nucleic acid encoding said light chain" refers to any light chain or only to the light chain from which the heavy chain is derived. Applicants respectfully submit that the Examiner has not indicated any basis for a lack of clarity. "Said light chain" clearly and unambiguously refers back to the light chain from the cell that expresses a heavy and light chain recited earlier in the claim. Withdrawal of the rejection is respectfully requested.

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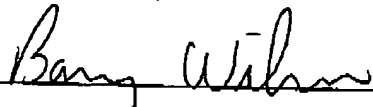
Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is urged to contact the undersigned by telephone to address any outstanding issues standing in the way of an allowance.

Respectfully submitted,

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Blood, 1977 Apr;49(4):495-505.

[Related Articles](#), [Links](#)

Gamma heavy chain disease: clinical aspects and characterization of a deleted, noncovalently linked gamma1 heavy chain dimer (BAZ).

Faguet GB, Barton BP, Smith LL, Garver FA.

This report describes the clinical and immunoglobulin features of a patient with gamma heavy chain disease (HCD), who presented with a clinical picture suggestive of an underlying malignancy rather than the usual picture of lymphoma or granulomatous disease. A unique clinical feature was the nearly total replacement of the submaxillary glands by plasma cells. The patient's serum and urine contained a paraprotein, gammaHCD protein BAZ, which belongs to the gamma1 subclass and forms noncovalently linked dimers with a molecular weight of approximately 60,000 daltons. This mutant protein exhibited a deletion which encompassed most of the variable (V) region, the first constant domain (CH 1), and the hinge region. In addition, preliminary structural analyses demonstrated the replacement of alanine by glycine in position 431 of the carboxyterminal octadecapeptide. This substitution may possibly represent another allotypic marker on IgG1 proteins.

EXHIBIT A

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